



IFW

Docket 17672 (BOT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: ERIC R. FIRST) Examiner:
Serial Number: 10/814,764) Art Unit:
Filed: March 30, 2004) Confirmation No.
For: PRESSURE SORE TREATMENT)
_____) Irvine, California

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

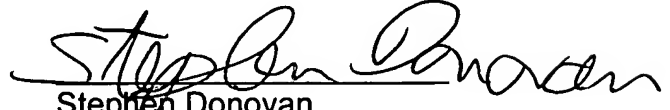
Applicants provide with regard to the patent application entitled PRESSURE SORE TREATMENT, filed herewith one copy of a documents of which they are aware, which may be material to the examination of this application, and in respect of which there may be a duty of disclosure under 37 C.F.R. §1.56. A listing of documents submitted is set forth on the attached Information Disclosure Citation (Form PTO-1449).

While these documents may be material pursuant to 37 C.F.R. §1.56, their disclosure is not intended to constitute an admission that the documents are prior art in regard to this invention. The filing of this Statement should not be construed to mean that a search has been conducted or that no other material documents or information exists. Please do not hesitate to contact the undersigned should any questions arise regarding this Statement.

The Commissioner is hereby authorized to charge any fees required or necessary for the filing, processing or entering of this paper or any of the enclosed papers, and to refund any overpayment, to deposit account 01-0885.

Respectfully submitted,

Date: July 20, 2004


Stephen Donovan
Registration Number 33,433

Please direct all inquiries and correspondence to:

Stephen Donovan
Allergan, Inc.
2525 Dupont Drive, T2-7H
Irvine, California 92623-9534
Tel: 714.246.4026
Fax: 714.246.4249

CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. § 1.10

I hereby certify that this Information Disclosure Statement and the documents referred to as enclosed herein are being deposited with the United States Postal Service on this date **May 27, 2004**, in an envelope as "Express Mail Post Office to Addressee" Mailing Label number EL 193 718 766 US addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Adriane Giberson
Name of person mailing paper


Signature of person mailing paper

Date: July 20, 2004





LIST OF ART CITED BY APPLICANT

ATTY. DOCKET: 17672 (BOT)	SERIAL NO.: 10/814,764
APPLICANT: ERIC R. FIRST	TITLE: PRESSURE SORE TREATMENT
FILING DATE: March 30, 2004	GROUP:

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA	2003/0224019	12/04/2003	O'Brien	424	239.1	
	AB	2004/0009180	01/15/2004	Donovan	424	184.1	
	AC	5,437,291	08/01/1995	Pasricha et al.	128	898	
	AD	5,670,484	09/23/1997	Binder	514	14	
	AE	5,714,468	02/03/1998	Binder	514	14	
	AF	5,766,605	06/16/1998	Sanders et al.	424	239.1	
	AG	5,989,545	11/23/1999	Foster et al.	424	183.1	
	AH	6,063,768	05/16/2000	First	514	14	
	AI	6,139,845	10/31/2000	Donovan	424	236.1	
	AJ	6,299,893 B1	10/09/2001	Schwartz et al.	424	422	
	AK	6,306,423 B1	10/23/2001	Donovan et al.	424	423	
	AL	6,312,708 B1	11/06/2001	Donovan	424	423	
	AM	6,423,319 B1	07/23/2002	Brooks et al.	424	239.1	
	AN	6,447,787	09/10/2002	Gassner et al.	424	247.1	
	AO	6,458,365 B1	10/01/2002	Aoki et al.	424	239.1	
	AP	6,464,986 B1	10/15/2002	Aoki et al.	424	239.1	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)
	BA	WO 03/011333	02/13/03	PCT	A61K	39/10	Y

OTHER ART

(Including Author, Title, Date, Pertinent Pages, etc.)

	CA	Andreadis S., et al., <i>Keratinocyte growth factor induces hyperproliferation and delays differentiation in a skin equivalent model system</i> , FASEB J. 2001 Apr;15(6):898-906
	CB	Aoki K., et al, <i>Mechanisms of the antinociceptive effect of subcutaneous Botox: Inhibition of peripheral and central nociceptive processing</i> , Cephalalgia 2003 Sep;23(7):649

EXAMINER _____ DATE CONSIDERED _____

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



LIST OF ART CITED BY APPLICANT

ATTY. DOCKET: 17672 (BOT)	SERIAL NO.: 10/814,764
APPLICANT: ERIC R. FIRST	TITLE: PRESSURE SORE TREATMENT
FILING DATE: March 30, 2004	GROUP:

	CC	Arredondo J., et al., <i>Central role of alpha7 nicotinic receptor in differentiation of the stratified squamous epithelium</i> , J Cell Biol. 2002 Oct 28;159(2):325-36
	CD	Asahina A., et al., <i>Specific induction of cAMP in Langerhans cells by calcitonin gene-related peptide: relevance to functional effects</i> , Proc Natl Acad Sci U S A. 1995 Aug 29;92(18):8323-7
	CE	Bigalke H., et al., <i>Botulinum A Neurotoxin Inhibits Non-Cholinergic Synaptic Transmission in Mouse Spinal Cord Neurons in Culture</i> , Brain Research 360;318-324:1985
	CF	Bigalke H., et al., <i>Tetanus Toxin and Botulinum A Toxin Inhibit Release and Uptake of Various Transmitters, as Studied with Particulate Preparations From Rat Brain and Spinal Cord</i> , Naunyn-Schmiedeberg's Arch Pharmacol 316;244-251:1981
	CG	Binz T., et al., <i>The Complete Sequence of Botulinum Neurotoxin Type A and Comparison with Other Clostridial Neurotoxins</i> , J Biological Chemistry 265(16):9153-9158:1990
	CH	Blugerman G., et al., <i>Multiple eccrine hidrocystomas: A new therapeutic option with botulinum toxin</i> , Dermatol Surg 2003 May;29(5):557-9
	CI	Borodic, Gary E., et al., <i>Pharmacology and Histology of the Therapeutic Application of Botulinum Toxin</i> , from Therapy with Botulinum Toxin, Ed. Jankovic J. et al., Marcel Dekker, Inc., (1994), page 150
	CJ	Brem, H., et al, <i>Placebo-Controlled Trial of Safety and Efficacy of Intraoperative Controlled Delivery by Biodegradable Polymers of Chemotherapy for Recurrent Gliomas</i> , Lancet 345;1008-1012:1995
	CK	Bushara K., <i>Botulinum toxin and rhinorrhea</i> , Otolaryngol Head Neck Surg 1996;114(3):507
	CL	Chen W., et al., <i>Trophic interactions between sensory nerves and their targets</i> , Journal of Biomedical Science. 1999;6(2):79-85
	CM	Chiang H-Y., et al., <i>Regional difference in epidermal thinning after skin denervation</i> , Exp Neurol 1998;154(1):137-45
	CN	Coffield J., et al., <i>The Site and Action of Botulinum Neuro-Toxin</i> , from Therapy with Botulinum Toxin, Ed. Jankovic J. et al., Marcel Dekker, Inc., (1994), page 5
	CO	Dabrowski E., et al, <i>Botulinum toxin as a novel treatment for self mutilation in Lesch-Nyhan syndrome</i> , Ann Neurol 2002 Sep;52(3 Supp 1):S157
	CP	Fung L. K., et al., <i>Pharmacokinetics of Interstitial Delivery of Carmustine 4-Hydroperoxycyclophosphamide and Paclitaxel From a Biodegradable Polymer Implant in the Monkey Brain</i> , Cancer Research 58;672-684:1998

EXAMINER _____

DATE CONSIDERED _____

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

LIST OF ART CITED BY APPLICANT

ATTY. DOCKET: 17672 (BOT)	SERIAL NO.: 10/814,764
APPLICANT: ERIC R. FIRST	TITLE: PRESSURE SORE TREATMENT
FILING DATE: March 30, 2004	GROUP:

	CQ	Gonelle-Gispert, Carmen, et al., <i>SNAP-25a and -25b Isoforms are Both Expressed in Insulin-Secreting Cells and Can Function in Insulin Secretion</i> , Biochem J. (1999) 339 (pt 1); pp. 159-65.
	CR	Grando S., <i>Biological functions of keratinocyte cholinergic receptors</i> , J Invest Dermatol Symp Proc. 1997 Aug;2(1):41-8
	CS	Grando S., et al., <i>Activation of keratinocyte nicotinic cholinergic receptors stimulates calcium influx and enhances cell differentiation</i> . Invest Dermatol. 1996 Sep;107(3):412-8
	CT	Grando S., et al., <i>Human keratinocytes synthesize, secrete, and degrade acetylcholine</i> J Invest Dermatol. 1993 Jul;101(1):32-6
	CU	Grando S., et al., <i>Keratinocyte muscarinic acetylcholine receptors: immunolocalization and partial characterization</i> , J Invest Dermatol. 1995 Jan;104(1):95-100
	CV	Griffin John W., et al., <i>Axonal Degeneration and Disorders of the Axonal Cytoskeleton</i> , <i>The Axon</i> , Ed. Waxman S., et al., New York: Oxford University Press, 1995; pp. 375-390.
	CW	Habermann E., et al., <i>Tetanus Toxin and Botulinum A and C Neurotoxins Inhibit Noradrenaline Release From Cultured Mouse Brain</i> , J Neurochem 51(2):522-527:1988
	CX	Habermann E., <i>I-Labeled Neurotoxin from Clostridium Botulinum A: Preparation, Binding to Synaptosomes and Ascent to the Spinal Column</i> , Naunyn-Schmiedeberg's Arch. Pharmacol. 1974; 281, pp. 47-56
	CY	Habermann E., <i>Inhibition by Tetanus and Botulinum A Toxin of the release of [3H]Noradrenaline and [3H]GABA From Rat Brain Homogenate</i> , Experientia 44:224-226:1988,
	CZ	<i>Harrison's Principles of Internal Medicine</i> (1998), edited by Anthony Fauci et al., 14th edition, published by McGraw Hill
	CAA	Heckmann M., et al., <i>Botulinum toxin type A injection in the treatment of lichen simplex: An open pilot study</i> , J Am Acad Dermatol 2002 Apr;46(4):617-9
	CBB	Hokfelt T., <i>Neuropeptides in perspective : The last ten years</i> , Neuron 1991; 7: 867-879
	CCC	Hosoi J., et al., <i>Regulation of Langerhans cell function by nerves containing calcitonin gene-related peptide</i> , Nature. 1993 May 13;363(6425):159-63
	CDD	Hsieh S., et al., <i>Epidermal denervation and its effects on keratinocytes and Langerhans cells</i> , J Neurocytol 1996;25:513-524

EXAMINER _____ DATE CONSIDERED _____

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

LIST OF ART CITED BY APPLICANT

ATTY. DOCKET: 17672 (BOT)	SERIAL NO.: 10/814,764
APPLICANT: ERIC R. FIRST	TITLE: PRESSURE SORE TREATMENT
FILING DATE: March 30, 2004	GROUP:

	CEE	Hsieh S., et al., <i>Modulation of keratinocyte proliferation by skin innervation</i> . Journal of Investigative Dermatology, 1999;113(4):579-86
	CFF	Hsieh S., et al., <i>Pathology of nerve terminal degeneration in the skin</i> , Journal of Neuropathology & Experimental Neurology. 2000;59(4):297-307
	CGG	Hsieh S., et al., <i>Skin Innervation and Its Effects on the Epidermis</i> , J Biomed Sci. 1997;4(5):264-268
	CHH	Hsiung-F., et al., (2001) <i>Quantitative pathology of cutaneous nerve terminal degeneration in the human skin</i> , Acta Neuropathologica 102:455-461
	CII	Huang T., et al., <i>Influence of cutaneous nerves on keratinocyte proliferation and epidermal thickness in mice</i> , Neuroscience 94 :965-973, 1999
	CJJ	Inaba N., et al., <i>Capsaicin-induced calcitonin gene-related peptide release from isolated rat stomach measured with a new chemiluminescent enzyme immunoassay</i> , Jpn J Pharmacol. 1996 Nov;72(3):223-9
	CKK	Jacks L., et al., <i>Idiopathic toe walking: Treatment with botulinum toxin A injection</i> , Dev Med Child Neurol 2002;44(Suppl 91):6
	CLL	Johnson M., <i>Synaptic glutamate release by postnatal rat serotonergic neurons in microculture</i> , Neuron 1994; 12: 433-442
	CMM	Jost W., <i>Ten years' experience with botulinum toxin in anal fissure</i> , Int J Colorectal Dis 2002 Sep;17(5):298-302
	CNN	Kaneko T., et al., <i>Immunohistochemical demonstration of glutaminase in catecholaminergic and serotonergic neurons of rat brain</i> , Brain Res. 1990; 507: 141-154
	COO	Kasakov L., et al., <i>Direct evidence for concomitant release of noradrenaline, adenosine 5'-triphosphate and neuropeptide Y from sympathetic nerve supplying the guinea-pig vas deferens</i> . J. Auton. Nerv. Syst. 1988; 22: 75-82
	CPP	Katsambas A., et al., <i>Cutaneous diseases of the foot: Unapproved treatments</i> , Clin Dermatol 2002 Nov-Dec;20(6):689-699
	CQQ	Ko M., et al., <i>Cutaneous nerve degeneration induced by acrylamide in mice</i> , Neuroscience Letters.(2000)293(3):195-8
	CRR	Komuves Laszlo et al., <i>Epidermal expression of the full-length extracellular calcium-sensing receptor is required for normal keratinocyte differentiation</i> , J. Cell Physiol. 2002 Jul;192(1); pp. 45-54
	CSS	Krnjevic K., <i>Central cholinergic mechanisms and function</i> . Prog Brain Res. 1993;98:285-92

EXAMINER _____

DATE CONSIDERED _____

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



LIST OF ART CITED BY APPLICANT

ATTY. DOCKET: 17672 (BOT)	SERIAL NO.: 10/814,764
APPLICANT: ERIC R. FIRST	TITLE: PRESSURE SORE TREATMENT
FILING DATE: March 30, 2004	GROUP:

	CTT	Kupfermann I., <i>Functional studies of cotransmission</i> , <i>Physiol. Rev.</i> 1991; Vol. 71, No. 3, July 1991; pp. 683-732.
	CUU	Lee M., et al., <i>Clinical and electrophysiological characteristics of inflammatory demyelinating neuropathies</i> , <i>Acta Neurol Taiwan</i> 1997;6:283-288
	CVV	Legat F., et al., <i>Repeated subinflammatory ultraviolet B irradiation increases substance P and calcitonin gene-related peptide content and augments mustard oil-induced neurogenic inflammation in the skin of rats</i> , <i>Neurosci Lett.</i> 2002 Sep 6;329(3):309-13
	CWW	Li Y., et al., <i>Sensory and motor denervation influences epidermal thickness in rat foot glabrous skin</i> , <i>Exp Neurol</i> 1997;147:452-462 (see page 459)
	CXX	Lin Y., et al., (2001) <i>Cutaneous nerve terminal degeneration in painful mononeuropathy</i> , <i>Experimental Neurology</i> . 170(2):290-6
	CYY	Lin Y., et al., <i>Quantitative sensory testing: normative values and its application in diabetic neuropathy</i> , <i>Acta Neurol Taiwan</i> 1998;7:176-184
	CZZ	Lundberg J., <i>Pharmacology of cotransmission in the autonomic nervous system: Integrative aspects on amines, neuropeptides, adenosine triphosphate, amino acids and nitric oxide</i> , <i>Pharmacol. Rev.</i> 1996; 48: 113-178
	CAAA	Marchese-Ragona, Rosario, et al., <i>Management of Parotid Sialoceles with Botulinum Toxin</i> , <i>The Laryngoscope</i> 109:1344-1346:1999
	CBBB	McCarthy B., et al., <i>Cutaneous innervation in sensory neuropathies: evaluation by skin biopsy</i> , <i>Neurol</i> 1995;45:1848-1855
	CCCC	<i>Mov Disord</i> , 10(3):376:1995
	CDDD	Moyer E. et al., <i>Botulinum Toxin Type B: Experimental and Clinical Experience</i> , being chapter 6, pages 71-85 of "Therapy With Botulinum Toxin", edited by Jankovic, J. et al. (1994), Marcel Dekker, Inc.
	CEEE	Naumann, Markus, et al., <i>Botulinum Toxin Type A in the Treatment of Focal, Axillary and Palmar Hyperhidrosis and Other Hyperhidrotic Conditions</i> , <i>European J. Neurology</i> 6 (Supp 4): S111-S1150:1999
	CFFF	Ndoye A., et al., <i>Identification and mapping of keratinocyte muscarinic acetylcholine receptor subtypes in human epidermis</i> , <i>J Invest Dermatol.</i> 1998 Sep;111(3):410-6
	CGGG	Nguyen V., et al., <i>Keratinocyte acetylcholine receptors regulate cell adhesion</i> <i>Life Sci.</i> 2003 Mar 28;72(18-19):2081-5

EXAMINER _____

DATE CONSIDERED _____

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



LIST OF ART CITED BY APPLICANT

ATTY. DOCKET: 17672 (BOT)	SERIAL NO.: 10/814,764
APPLICANT: ERIC R. FIRST	TITLE: PRESSURE SORE TREATMENT
FILING DATE: March 30, 2004	GROUP:

	CHHH	Nguyen V., et al., <i>Programmed cell death of keratinocytes culminates in apoptotic secretion of a humectant upon secretagogue action of acetylcholine</i> J Cell Sci. 2001 Mar;114(Pt 6):1189-204
	CIII	Nicholas A., et al., <i>Glutamate-like immunoreactivity in medulla oblongata catecholamine/substance P neurons</i> , NeuroReport 1990; 1: 235-238
	CJJJ	Nicholas A., et al., <i>Serotonin-, Substance P- and Glutamate/Aspartate-like Immunoreactivities in Medullo-Spinal Pathways of Rat and Primate</i> , Neuroscience, Vol. 48, No. 3, pp. 545-559
	CKKK	Palacios J., et al., <i>Cholinergic neuropharmacology: an update</i> , Acta Psychiatr Scand Suppl. 1991;366:27-33
	CLLL	Pan C., et al., (2001) <i>Degeneration of nociceptive nerve terminals in human peripheral neuropathy</i> , Neuroreport. 12(4):787-92
	CMMN	Pearce L.B., <i>Pharmacologic Characterization of Botulinum Toxin For Basic Science and Medicine</i> , Toxicon 35(9);1373-1412 at 1393
	CNNN	Rogers J., et al., <i>Injections of botulinum toxin A in foot dystonia</i> , Neurology 1993 Apr;43(4 Suppl 2)
	COOO	Sanchez-Prieto J., et al., <i>Botulinum Toxin A Blocks Glutamate Exocytosis From Guinea Pig Cerebral Cortical Synaptosomes</i> , Eur J. Biochem 165;675-681:1897
	CPPP	Schantz E.J., et al, <i>Properties and use of Botulinum toxin and Other Microbial Neurotoxins in Medicine</i> , Microbiol Rev. 56;80-99:1992
	CQQQ	Sevim S., et al., <i>Botulinum toxin-A therapy for palmar and plantar hyperhidrosis</i> , Acta Neurol Belg 2002 Dec;102(4):167-70
	CRRR	Singh, <i>Critical Aspects of Bacterial Protein Toxins</i> , pages 63-84 (chapter 4) of Natural Toxins II, edited by B.R. Singh et al., Plenum Press, New York (1976)
	CSSS	Sloop, R. Richard, et al., <i>Reconstituted Botulinum Toxin Type A Does Not Lose Potency in Humans if it is Refrozen or Refrigerated for 2 Weeks Before Use</i> , Neurology, 48:249-53:1997
	CTTT	Sneddon P., et al., <i>Pharmacological evidence that adenosine triphosphate and noradrenaline are cotransmitters in the guinea-pig vas deferens</i> . J. Physiol. 1984; 347: 561-580
	CUUU	Suputtitada A., <i>Local botulinum toxin type A injections in the treatment of spastic toes</i> , Am J Phys Med Rehabil 2002 Oct;81(10):770-5
	CVVV	Weigand et al, <i>Nauny-Schmiedeberg's Arch. Pharmacol.</i> 1976; 292, 161-165
	CWWV	Whitehouse P., et al., <i>Nicotinic and muscarinic cholinergic receptors in Alzheimer's disease and related disorders</i> , J Neural Transm Suppl. 1987;24:175-82

EXAMINER _____ DATE CONSIDERED _____

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



LIST OF ART CITED BY APPLICANT

ATTY. DOCKET: 17672 (BOT)	SERIAL NO.: 10/814,764
APPLICANT: ERIC R. FIRST	TITLE: PRESSURE SORE TREATMENT
FILING DATE: March 30, 2004	GROUP:

	CXXX	Wu T., et al., <i>Demonstration of human papillomavirus (HPV) genomic amplification and viral-like particles from CaSki cell line in SCID mice</i> , J Virol Methods 1997;65:287-298
	CYYY	Xu Z-QD., et al., <i>Galanin/GMAP- and NPY-like immunoreactivities in locus coeruleus and noradrenergic nerve terminals in the hippocampal formation and cortex with notes on the galanin-R1 and - R2 receptors</i> , J. Comp. Neurol. 1998; 392: 227-252
	CZZZ	Xu Z-QD., et al., <i>Galanin-5-hydroxytryptamine interactions: Electrophysiological, immunohistochemical and in situ hybridization studies on rat dorsal raphe neurons with a note on galanin R1 and R2 receptors</i> . Neuroscience 1998; 87: 79-94
	CAAA	Zia S., et al., <i>Receptor-mediated inhibition of keratinocyte migration by nicotine involves modulations of calcium influx and intracellular concentration</i> , J Pharmacol Exp Ther. 2000 Jun;293(3):973-81

EXAMINER _____ DATE CONSIDERED _____

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

